



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-1173]

Electronic Submission of Expedited Safety Reports from Investigational New Drug-Exempt Bioavailability/Bioequivalence Studies; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Electronic Submission of Expedited Safety Reports From IND-Exempt BA/BE Studies.” This guidance provides instructions for the electronic submission of expedited individual case safety reports (ICSRs) from investigational new drug (IND)-exempt bioavailability (BA)/bioequivalence (BE) studies through the FDA Adverse Event Reporting System (FAERS) database.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be

posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2022-D-1173 for "Electronic Submission of Expedited Safety Reports from IND-Exempt BA/BE Studies." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy,

including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Susan Levine, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1674, Silver Spring, MD 20993-0002, 240-402-7936, Susan.Levine@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Electronic Submission of Expedited Safety Reports from IND-Exempt BA/BE Studies.” This guidance provides instructions for the electronic submission of expedited ICSRs from IND-exempt BA/BE studies through the FAERS database. An ICSR captures information necessary to support the reporting of an adverse event related to an individual subject that is associated with the use of an FDA-regulated product.¹ The electronic submission of the ICSRs from IND-exempt BA/BE studies is a voluntary option.

In the *Federal Register* of September 29, 2010 (75 FR 59935), FDA published a final rule that revised the IND safety reporting requirements for human drug and biological products under 21 CFR 312 and added safety reporting requirements for persons conducting IND-exempt BA/BE studies under 21 CFR 320.31.² A serious adverse event experienced by a study subject during the conduct of an IND-exempt BA/BE study must be submitted on Form FDA 3500A or in an electronic format that FDA can process, review, and archive.³

Previously, to meet the requirements under § 320.31(d)(3) applicable to IND-exempt BA/BE studies, submitters sent expedited premarket safety reports directly to the Office of Generic Drugs (OGD) by email, telephone, or facsimile. This guidance provides recommendations on how to electronically submit ICSRs to the FAERS database as an alternate avenue for submitting reports to OGD once these enhancements are activated.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Electronic Submission of Expedited Safety Reports From IND-Exempt

¹ See additional information on Individual Case Safety Reports available at <https://www.fda.gov/industry/fda-resources-data-standards/individual-case-safety-reports>.

² BA and BE studies that meet the conditions for exemption under 21 CFR 320.31 are not conducted under an IND and are not subject to the IND safety reporting requirements. The safety reporting requirements under § 320.31(d)(3) apply to persons conducting BA or BE studies that are exempt from the IND requirements.

³ 21 CFR 320.31(d)(3).

BA/BE Studies.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 for IND applications and 21 CFR 320.31 for IND-exempt BA/BE safety reporting requirements for human drug and biological products have been approved under OMB control number 0910-0014. The collections of information in 21 CFR 314 for safety report submissions for applications for FDA approval new drug application have been approved under OMB control number 0910-0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: July 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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